

In the Claims

Claim 1 (Currently amended): ~~An~~ A biomimetic organic/inorganic composite comprising:  
~~an organic~~ a fluid-swellable, fibrous organic matrix comprising fibers and interstitial spaces;  
and

an inorganic mineral phase of amorphous or crystalline structure that coats and infiltrates each of said fibers, wherein said inorganic mineral phase is deposited on and absorbed within said fluid-swellable, fibrous matrix when said inorganic mineral phase is in the form of a liquid phase mineral precursor, and wherein said inorganic mineral phase is aligned along the long axis of each of the fibers of said fluid-swellable, fibrous matrix that said inorganic mineral phase is deposited and is embedded in said interstitial spaces.

Claim 2 (Currently amended): The organic/inorganic composite of claim 1, wherein the fibers of said fluid-swellable, fibrous organic matrix are substantially parallel to one another.

Claim 3 (Currently amended): The organic/inorganic composite of claim 1, wherein said ~~fluid-swellable, fibrous matrix comprises an interior with interstitial space, and wherein said inorganic mineral phase is absorbed into said interstitial space when said inorganic mineral phase is in the form of a liquid phase mineral precursor, which subsequently solidifies~~ each of said fibers comprises fibrils, wherein said interstitial spaces comprise gaps and grooves in and between said fibrils, and wherein said inorganic mineral phase is embedded in said gaps and grooves.

Claim 4 (Cancelled)

Claim 5 (Currently amended): The organic/inorganic composite of claim 4, wherein said ~~inorganic liquid-phase mineral precursor deposited on said fluid-swellable, fibrous matrix has a non-faceted topography when said liquid-phase mineral precursor becomes solidified~~ inorganic mineral phase comprises crystals that are non-faceted.

Claim 6 (Currently amended): The organic/inorganic composite of claim 1, wherein said fibers comprise a long axis, and wherein said inorganic mineral phase comprises hydroxyapatite crystals oriented in the [001] crystallographic direction along the long axis of each of the fibers of said fluid swellable, fibrous organic matrix.

Claim 7 (Cancelled)

Claim 8 (Currently amended): The organic/inorganic composite of claim 1, wherein said fluid-swellable, fibrous organic matrix comprises at least one material selected from the group consisting of collagen, elastin, chitin, cellulose, chitosan, and peptide nanofibers.

Claim 9 (Currently amended): The organic/inorganic composite of claim 1, wherein said fluid-swellable, fibrous organic matrix has been ~~surfaced-modified~~ surface modified.

Claim 10 (Cancelled)

Claim 11 (Currently amended): The organic/inorganic composite of claim 1, wherein said fluid-swellable, fibrous organic matrix comprises collagen.

Claim 12 (Original): The organic/inorganic composite of claim 11, wherein said collagen is selected from the group consisting of collagen type 1, collagen type 2, collagen type 3, collagen type 4, collagen type 5, collagen type 6, collagen type 7, collagen type 8, collagen type 9, collagen type 10, collagen type 11, collagen type 12, collagen type 13, collagen type 14, collagen type 15, collagen type 16, collagen type 17, collagen type 18, collagen type 19, and collagen type 20, or combinations thereof.

Claim 13 (Currently amended): The organic/inorganic composite of claim 11, wherein said collagen comprises collagen fibers, wherein each of said fibers comprises abutting fibrils with gaps

~~arranged between said abutting fibrils, and wherein said liquid phase mineral precursor is absorbed into said gaps by capillarity, and wherein said inorganic mineral phase is aligned along the long axis of each of said fibrils gaps and/or grooves arranged within and between said abutting fibrils, and wherein said inorganic mineral phase is embedded within said gaps and/or grooves.~~

Claim 14 (Original): The organic/inorganic composite of claim 11, wherein said collagen has been surface modified.

Claim 15 (Original): The organic/inorganic composite of claim 1, wherein said inorganic mineral phase comprises at least one member selected from the group consisting of calcium phosphate, calcium carbonate, hydroxyapatite, strontium carbonate, calcium sulfate, calcium oxalate, magnesium-bearing calcium carbonate, and magnesium-bearing calcium phosphate.

Claim 16 (Original): The organic/inorganic composite of claim 1, wherein said inorganic mineral phase comprises at least one member selected from the group consisting of hydroxyapatite, octacalcium phosphate, tricalcium phosphate, carbonated hydroxyapatite, fluorinated hydroxyapatite, brushite, magnesium containing hydroxyapatite, dicalcium phosphate dihydrate, and amorphous calcium phosphate.

Claim 17 (Cancelled)

Claim 18 (Currently amended): The organic/inorganic composite of claim 1, ~~wherein said fluid swellable, fibrous matrix comprises collagen fibers~~ wherein said fibers are collagen fibers having a long axis, wherein each of said fibers comprises abutting fibrils having a long axis, and wherein said inorganic mineral phase comprises hydroxyapatite crystals oriented in the [001] crystallographic direction along the long axis of each of said collagen fibers and each of said fibrils.

Claim 19 (Currently amended): The organic/inorganic composite of claim 1, wherein said composite further comprises one or more biologically active agents on or within said composite.

Claim 20 (Original): The organic/inorganic composite of claim 19, wherein said one or more biologically active agents are selected from the group consisting of medicaments; vitamins; mineral supplements; substances used for the treatment, prevention, diagnosis, cure or mitigation of disease or illness; substances affecting the structure or function of the body; drugs; antimicrobial agents; antifungal agents; antibacterial agents; antiviral agents; antiparasitic agents; growth factors; angiogenic factors; anaesthetics; mucopolysaccharides; metals; cells; acid mucopolysaccharides; proteins; enzymes, peptides; and wound healing agents.

Claim 21 (Original): The organic/inorganic composite of claim 20, wherein said one or more biologically active agents are seeded on said composite or embedded within said composite.

Claim 22 (Currently amended): The organic/inorganic composite of claim 20, wherein said one or more biologically active agents are pendantly attached to said ~~organic~~ fluid-swellable, fibrous organic matrix or said inorganic mineral phase.

Claim 23 (Currently amended): The organic/inorganic composite of claim 20, wherein said one or more biologically active agents are embedded within said organic fluid-swellable, fibrous organic matrix, or said inorganic mineral phase, or both.

Claim 24 (Currently amended): The organic/inorganic composite of claim 1, wherein said organic/inorganic composite is in a form selected from the group consisting of an injectable liquid, a malleable paste, a malleable putty, a particulate, a film, a coating, a molded solid, and a preformed solid.

Claims 25 - 26 (Cancelled)

Claim 27 (Original): The organic/inorganic composite of claim 1, wherein said organic/inorganic composite is porous.

Claim 28 (Original): The organic/inorganic composite of claim 27, wherein said pores range from about 50 microns to about 500 microns or more in diameter.

Claim 29 (Currently amended): The organic/inorganic composite of claim 1, wherein said ~~organic~~ fluid-swellaable, fibrous organic matrix is porous.

Claim 30 (Cancelled)

Claim 31 (Currently amended): The organic/inorganic composite of claim 1, wherein said ~~organic substrate~~ fluid-swellaable, fibrous organic matrix is biocompatible and bioresorbable.

Claim 32 (Currently amended): The organic/inorganic composite of claim 1, ~~wherein said fluid-swellaable matrix comprises a scaffold seeded with cells~~ further comprising cells seeded on said composite.

Claim 33 (Currently amended): The organic/inorganic composite of claim 32, wherein said cells are selected from the group consisting of bone marrow stem cells, osteoblasts, osteoclasts, osteocytes, blood cells, epithelial cells, odontoblasts, ameloblasts, cementoblasts, and neural cells.

Claim 34 (Currently amended): The organic/inorganic composite of claim 1, wherein said ~~organic~~ fluid-swellaable, fibrous organic matrix comprises a film or coating.

Claim 35 (Currently amended): The organic/inorganic composite of claim 1, wherein said composite comprises a plurality of said ~~organic substrates~~ fluid-swellaable, fibrous organic matrices arranged as lamellae.

Claim 36 (Currently amended): The organic/inorganic composite of claim 35, wherein said lamellae are arranged concentrically around a central void, ~~in an osteon-like structure.~~

Claim 37 (Currently amended): The organic/inorganic composite of claim 1, wherein said composite comprises a plurality of said ~~organic~~-fluid-swellable, fibrous organic matrices, and wherein said composite further comprises an adhesive layer between each of said ~~organic~~-fluid-swellable, fibrous organic matrices.

Claim 38 (Currently amended): The organic/inorganic composite of claim 37, ~~wherein said plurality of organic substrates have a parallel orientation~~ wherein said fibers of said plurality of fluid-swellable, fibrous organic matrices are oriented in parallel.

Claim 39 (Currently amended): The organic/inorganic composite of claim 37, ~~wherein said plurality of organic substrates are arranged in an alternating orientation~~ wherein said fibers of each of said fluid-swellable, fibrous matrices are oriented in parallel, and wherein said fibers of adjacent fluid-swellable, fibrous organic matrices are not parallel with each other.

Claim 40 (Withdrawn-Currently amended): A process for making ~~organic/inorganic~~ composites a biomimetic organic/inorganic composite of claim 1, said method comprising contacting an acidic polymer with a mineralizing solution under conditions suitable to form an inorganic liquid-phase mineral precursor, and contacting said inorganic liquid-phase mineral precursor with an ~~organic~~ a fluid-swellable, fibrous organic matrix, wherein said inorganic liquid-phase mineral precursor ~~is absorbed into, and subsequently hardens within, said fluid-swellable, fibrous matrix, and wherein said hardened inorganic liquid-phase mineral precursor is aligned along the long axis of each of the fibers of said fluid-swellable, fibrous matrix to which said precursor is contacted~~ coats and infiltrates each fiber of said fluid-swellable, fibrous organic matrix, penetrating said interstitial spaces of said fibers, forming said inorganic mineral phase of amorphous crystalline structure.

Claim 41 (Withdrawn): The process according to claim 40, wherein said acidic polymer has a molecular weight in the range of about 1000 to about 100,000 g/mol.

Claim 42 (Withdrawn-Currently amended): The process according to claim 40, wherein said ~~second contacting step is repeated until said organic fluid-swellable matrix is sufficiently mineralized~~ contacting of said liquid phase mineral precursor with said fluid-swellable, fibrous organic matrix is repeated until said fluid-swellable, fibrous organic matrix is sufficiently mineralized.

Claim 43 (Withdrawn): The process according to claim 40, wherein said acidic polymer comprises at least one member selected from the group consisting of polyacrylic acid, polymethacrylic acid, sulfonated polymers, phosphorylated proteins or peptides, phosphorylated polymers, sulfated polysaccharides, sulfated glycoproteins, polyaspartic acid, polyglutamic acid, polyaspartate, polyvinyl phosphate, and polyvinyl phosphonate, or combinations thereof.

Claim 44 (Withdrawn-Currently amended): The process according to claim 40, wherein said fluid-swellable, fibrous organic matrix comprises a material selected from at least one member of the group consisting of collagen, elastin, chitin, chitosan, cellulose, and peptide nanofibers.

Claim 45 (Withdrawn-Currently amended): The process according to claim 40, wherein said fluid-swellable, fibrous organic matrix comprises collagen fibers.

Claim 46 (Withdrawn): The process according to claim 40, wherein said collagen is selected from the group consisting of collagen type 1, collagen type 2, collagen type 3, collagen type 4, collagen type 5, collagen type 6, collagen type 7, collagen type 8, collagen type 9, collagen type 10, collagen type 11, collagen type 12, collagen type 13, collagen type 14, collagen type 15, collagen type 16, collagen type 17, collagen type 18, collagen type 19, and collagen type 20, or combinations thereof.

Claim 47 (Withdrawn): The process according to claim 40, wherein said inorganic liquid-phase mineral precursor comprises at least one member selected from the group consisting of calcium phosphate, calcium carbonate, hydroxyapatite, strontium carbonate, and calcium sulfate, calcium oxalate, magnesium-bearing calcium carbonate, and magnesium-bearing calcium phosphate.

Claim 48 (Withdrawn): The process according to claim 40, wherein said inorganic liquid-phase mineral precursor comprises at least one member selected from the group consisting of hydroxyapatite, octacalcium phosphate, tricalcium phosphate, carbonated hydroxyapatite, fluorinated hydroxyapatite, brushite, magnesium containing hydroxyapatite, dicalcium phosphate dihydrate, and amorphous calcium phosphate.

Claim 49 (Withdrawn): The process according to claim 40, wherein said method further comprises associating a biologically active agent within said composite.

Claim 50 (Withdrawn): The process according to claim 49, wherein said biologically active agents comprise at least one member selected from the group consisting of medicaments; vitamins; mineral supplements; substances used for the treatment, prevention, diagnosis, cure or mitigation of disease or illness; substances affecting the structure or function of the body; drugs; antimicrobial agents; antifungal agents; antibacterial agents; antiviral agents; antiparasitic agents; growth factors; angiogenic factors; anaesthetics; mucopolysaccharides; metals; cells; acid mucopolysaccharides; proteins; enzymes, peptides; and wound healing agents.

Claim 51 (Withdrawn): The process according to claim 40, wherein said inorganic liquid-phase mineral precursor is formed by combining calcium salt and said acidic polymer to form an aqueous solution, and reacting said aqueous solution with ammonium carbonate vapor or ammonium phosphate vapor.

Claim 52 (Withdrawn): The process according to claim 51, wherein the aqueous solution is reacted with the ammonium carbonate vapor, and wherein the ammonium carbonate vapor is



provided through the decomposition of at least one ammonium carbonate material selected from the group consisting of ammonium carbonate monohydrate, ammonium carbonate dihydrate, and ammonium carbamate.

Claim 53 (Withdrawn): The process according to claim 51, wherein the aqueous solution is reacted with the ammonium phosphate vapor, and wherein the ammonium phosphate vapor is provided through the decomposition of at least one ammonium phosphate material selected from the group consisting of ammonium phosphate monobasic, ammonium phosphate dibasic.

Claim 54 (Withdrawn): The process according to claim 40, wherein said inorganic liquid-phase mineral precursor is formed by combining calcium chloride and a combination of acidic polymers to form an aqueous solution, and reacting said aqueous solution with ammonium phosphate vapor.

Claim 55 (Withdrawn): The process according to claim 40, wherein said inorganic liquid-phase mineral precursor is formed by combining calcium chloride and a combination of acidic polymers to form an aqueous solution, and reacting said aqueous solution with a phosphate containing solution.

Claim 56 (Withdrawn): The process according to claim 40, wherein said inorganic liquid-phase mineral precursor is formed by combining calcium salt and a combination of acidic polymers to form an aqueous solution, and reacting said aqueous solution with phosphate generated by enzymatic degradation of phosphate containing compounds.

Claim 57 (Withdrawn): The process according to claim 40, wherein said inorganic liquid-phase mineral precursor is formed by combining calcium salt and ammonium phosphate, and a combination of acidic polymers to form an aqueous solution, in which precipitation is caused by a change of temperature, change of pH, evaporation, or removal of crystallization inhibitor.

Claim 58 (Withdrawn): The process according to claim 40, wherein said fluid-swellaable, fibrous matrix comprises an exterior surface and an interior containing an interstitial space, wherein said inorganic liquid-phase mineral precursor is absorbed into said interstitial space of said fluid-swellaable, fibrous matrix, and deposited onto said exterior surface of said fluid-swellaable, fibrous matrix; and wherein said liquid-phase mineral precursor deposited onto said exterior surface of said fluid-swellaable matrix has a non-faceted topography when solidified.

Claims 59-61 (Cancelled)

Claim 62 (Withdrawn-Currently amended): A method for treating a bone defect, comprising applying ~~an~~ a biomimetic organic/inorganic composite of claim 1 to the site of the bone defect; ~~wherein said organic/inorganic composite comprises a fluid swellaable, fibrous matrix and an inorganic mineral phase, and wherein said inorganic mineral phase is absorbed into said fluid-swellaable, fibrous matrix when said inorganic mineral phase is in the form of a liquid-phase mineral precursor, which subsequently solidifies and is aligned along the long axis of each of the fibers of said fluid-swellaable, fibrous matrix to which said inorganic mineral phase is absorbed.~~

Claim 63 (Withdrawn): The method according to claim 62, wherein said organic/inorganic composite is applied as an injectable liquid, a film, a malleable putty, a malleable paste, a particulate, or a molded or preformed solid.

Claim 64 (Withdrawn-Currently amended): The method according to claim 62, wherein said fluid-swellaable, organic fibrous matrix comprises a material selected from the group consisting of collagen, elastin, chitin, chitosan, cellulose, and peptide nanofibers.

Claim 65 (Withdrawn): The method according to claim 62, wherein said inorganic mineral is selected from the group consisting of calcium phosphate, calcium carbonate, hydroxyapatite, strontium carbonate, and calcium sulfate, calcium oxalate, magnesium-bearing calcium carbonate, and magnesium-bearing calcium, or combinations thereof.

Claim 66 (Withdrawn-Currently amended): The method according to claim 62, wherein said organic/inorganic composite further comprises a biologically active agent on or within said composite.

Claim 67 (Withdrawn): The method according to claim 62, wherein said organic/inorganic composite is porous.

Claim 68 (Withdrawn): The method according to claim 62, wherein said organic substrate is biocompatible and bioresorbable.

Claim 69 (Withdrawn-Currently amended): The method according to claim 62, wherein said ~~fluid-swellable, fibrous matrix comprises a scaffold seeded with cells~~ composite further comprises cells seeded on said composite.

Claim 70 (Withdrawn): The method according to claim 69, wherein said cells are selected from the group consisting of bone marrow stem cells, osteoblasts, osteoclasts, osteocytes, blood cells, epithelial cells, odontoblast, ameloblasts, and neural cells, or combinations thereof.

Claim 71 (Withdrawn-Currently amended): The method according to claim 62, wherein said fluid-swellable, fibrous organic matrix is a film or coating.

Claim 72 (Withdrawn-Currently amended): The method according to claim 62, wherein said organic/inorganic composite comprises a plurality of said fluid-swellable, fibrous organic matrices arranged as laminae.

Claim 73 (Withdrawn): The method according to claim 72, wherein said lamellae are arranged concentrically around a central void for passage of endogenous or exogenous cells.

Claim 74 (Withdrawn-Currently amended): The method according to claim 62, wherein said organic/inorganic composite comprises a plurality of said fluid-swellable, fibrous organic matrices, and wherein said organic/inorganic composite further comprises an adhesive layer between each of said ~~organic substrates~~ fluid-swellable, fibrous organic matrices.

Claims 75 - 76 (Cancelled)

Claim 77 (New): The biomimetic organic/inorganic composite of claim 1, wherein said inorganic mineral phase has an amorphous structure.

Claim 78 (New): The biomimetic organic/inorganic composite of claim 1, wherein said inorganic mineral phase has a crystalline structure.

Claim 79 (New): The biomimetic organic/inorganic composite of claim 1, wherein said fibers of said fluid-swellable, fibrous organic matrix are fibrils.